



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0313]

Guidance for Industry: Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation." The document provides guidance to egg producers on how to comply with certain provisions contained in FDA's final rule "Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation" (the final rule), including how to implement Salmonella Enteritidis (SE) prevention measures, how to sample for SE, and how to maintain records documenting compliance with the final rule.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Plant and Dairy Food Safety/Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS-315), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Nancy Bufano,
Center for Food Safety and Applied Nutrition (HFS-316),
Food and Drug Administration,
5100 Paint Branch Pkwy.,
College Park, MD 20740,
240-402-1493.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of July 9, 2009 (74 FR 33030), FDA issued a final rule requiring shell egg producers to implement measures to prevent SE from contaminating eggs on the farm and from further growth during storage and transportation, to maintain records concerning their compliance with the final rule, and to register with FDA. This final rule became effective September 8, 2009. In the Federal Register of August 12, 2010 (75 FR 48973), FDA made available a draft guidance entitled "Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation" and gave interested parties an opportunity to submit comments by October 12, 2010. The Agency reviewed and evaluated these comments and has modified the guidance where appropriate.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on how to comply with

certain SE prevention measures, how to sample for SE, and how to maintain records documenting compliance with the final rule. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 118.5, 118.6, 118.10, and 118.11 have been approved under OMB control number 0910-0660.

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding the guidance. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Always access an FDA document using the FDA Web site listed previously to find the most current version of the guidance.

Dated: December 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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